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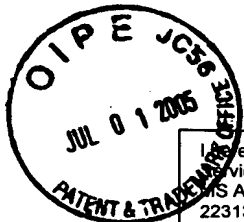
PTO/SB/21 (09-04)  
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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/759381-Conf. #6695	
	Filing Date	January 15, 2004	
	First Named Inventor	Raphael J. MANNINO	
	Art Unit	1614	
	Examiner Name	Not Yet Assigned	
Total Number of Pages in This Submission	1	Attorney Docket Number	BSZ-017

ENCLOSURES (Check all that apply)		
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	LAHIVE & COCKFIELD, LLP		
Signature			
Printed name	Danielle L. Herritt		
Date	June 29, 2005	Reg. No.	43,670

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(Danielle L. Herritt)

Docket No.: BSZ-017  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Raphael J. Mannino *et al.*

Application No.: 10/759381

Confirmation No.: 6695

Filed: January 15, 2004

Art Unit: 1614

For: COCHLEATE PREPARATIONS OF  
FRAGILE NUTRIENTS

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment  
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P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. A copy of references A24-C5 on the PTO/SB/08 are attached.

Documents A16 and A25-A30 of the attached SB/08 were cited in an International Search Report issued June 22, 2004, during the prosecution of international application no. PCT/US2004/001236, which corresponds to the above referenced application. In accordance with 37 CFR 1.97(c) and (e)(1) or (b)(3), Applicant hereby submit(s) these documents for the Examiner's consideration. A copy of the International Search Report and of each document required under 37 CFR 1.98(a)(2) cited thereon are enclosed as well. It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

In addition, Applicant directs the Examiner's attention to the following United States patent applications.

U.S. Ser. No.	Filing Date
11/042,598	01/24/05
11/040,615	01/18/05
10/304,567	11/26/02
10/701,364	11/03/03
11/051,562	02/03/05
11/047,373	01/28/05
10/822,235	04/09/04
10/822,230	04/09/04

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such. Moreover, Applicant(s) understand(s) the Examiner will make an independent evaluation of the cited documents.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 12-0080, under Order No. BSZ-017. A duplicate copy of this paper is enclosed.

Dated: June 29, 2005

Respectfully submitted,

By 

Danielle L. Herritt

Registration No.: 43,670

LAHIVE & COCKFIELD, LLP

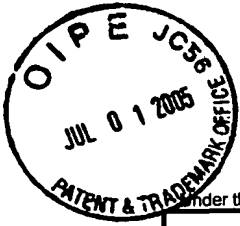
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Attorney/Agent For Applicant



Application No. (if known): 10/759381

Attorney Docket No.: BSZ-017

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PTO/SB/08a/b (08-03)  
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<b>Substitute for form 1449A/B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/759381-Conf. #6695
				Filing Date	January 15, 2004
				First Named Inventor	Raphael J. MANNINO
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	1	of	3	Attorney Docket Number	BSZ-017

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1	4,078,052	03-07-1978	Papahadjopoulos	
	A2	4,663,161	05-05-1987	Mannino <i>et al.</i>	
	A3	4,725,442	02-16-1988	Haynes	
	A4	4 871 488	10-03-1989	Mannino <i>et al.</i>	
	A5	4,874,795	10-17-1989	Yesair	
	A6	4 990 291	02-05-1991	Schoen <i>et al.</i>	
	A7	5 269 979	12-14-1993	Fountain	
	A8	5,571,517	11-05-1996	Yesair	
	A9	5,580,859	12-03-1996	Feigner <i>et al.</i>	
	A10	5,589,466	12-31-1996	Feigner <i>et al.</i>	
	A11	5 643 574	07-01-1997	Gould - Fogerite <i>et al.</i>	
	A12	5,834,015	11-10-1998	Oleske <i>et al.</i>	
	A13	5,840,707	11-24-1998	Mannino <i>et al.</i>	
	A14	5,994,318	11-30-1999	Gould - Fogerite <i>et al.</i>	
	A15	6,120,751	11-19-2000	Unger	
	A16	6,153,217	11-28-2000	Jin <i>et al.</i>	
	A17	6,165,502	12-26-2000	Oleske <i>et al.</i>	
	A18	6,340,591	01-22-2002	Margolis <i>et al.</i>	
	A19	6,403,056	06-11-2002	Unger	
	A20	6,447,800	09-10-2002	Hope	
	A21	6,592,894	07-15-2003	Zarif <i>et al.</i>	
	A22	6,808,720	10-26-2004	Unger	
	A23	US2003/0219473	11-27-2003	Zarif <i>et al.</i>	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	A24	FR 2 221 122 A	10-11-1974	Bayer AG		Abs
	A25	WO 92 03121	03-05-1992	Yesair		
	A26	WO 95 09648	04-13-1995	Gould-Fogerite <i>et al.</i>		
	A27	WO 96 25942	08-29-1996	Albany Medical College <i>et al.</i>		
	A28	WO 97 30725	08-28-1997	Mannino <i>et al.</i>		
	A29	WO 00 42989	07-27-2000	Biodelivery Sciences, Inc. <i>et al.</i>		
	A30	WO 01 52817	07-26-2001	Biodelivery Sciences, Inc. <i>et al.</i>		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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Substitute for form 1449A/B/PTO  <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;">(Use as many sheets as necessary)</p>				<b>Complete if Known</b>	
		Application Number	10/759381-Conf. #6695		
		Filing Date	January 15, 2004		
		First Named Inventor	Raphael J. MANNINO		
		Art Unit	1614		
		Examiner Name	Not Yet Assigned		
Sheet	2	of	3	Attorney Docket Number	BSZ-017

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	B1	ASAI, "Formation of the dispersed particles composed of retinol and phosphatidylcholine," <i>Int J Pharm</i> , 253: 89-95, 2003.		
	B2	GOULD-FOGERITE <i>et al.</i> Chimerasome-mediated gene transfer in vitro and in vivo. <i>Gene</i> . 84(2):429-38, 1989.		
	B3	GOULD-FOGERITE <i>et al.</i> Rotary dialysis: its application to the preparation of large liposomes and large proteoliposomes (protein-lipid vesicles) with high encapsulation efficiency and efficient reconstitution of membrane proteins. <i>Anal Biochem</i> . 148(1):15-25, 1985.		
	B4	GOULD-FOGERITE <i>et al.</i> The reconstitution of biologically active glycoproteins into large liposomes: use as a delivery vehicle to animal cells. <i>Adv Memb Biochem Bioener</i> . 569-586, 1988.		
	B5	GOULD-FOGERITE <i>et al.</i> Liposome preparation and related techniques. <i>Liposome Technology</i> , 2 <sup>nd</sup> Edition. 1:67-80, 1993.		
	B6	GOULD-FOGERITE <i>et al.</i> Interaction of liposomes with the biological milieu. <i>Liposome Technology</i> , 2 <sup>nd</sup> Edition. 3:261-276, 1993.		
	B7	GOULD-FOGERITE <i>et al.</i> "Mucosal and systemic immunization using cochleate and liposome vaccines" <i>J. Liposome Res</i> , 6(2): 357-79, 1996.		
	B8	GOULD-FOGERITE <i>et al.</i> , "Targeting immune response induction with cochleate and liposome-based vaccines" <i>Adv Drug Delivery Rev</i> , 32(3), pgs. 273-287, 1998.		
	B9	GOULD-FOGERITE <i>et al.</i> Cochleates for induction of mucosal and systemic immune responses. <i>Meth Molec Med</i> 42: 179-196, 1999.		
	B10	GOULD-FOGERITE <i>et al.</i> , Cochleate Delivery Vehicles: Applications in Vaccine Delivery. <i>J Liposome Res</i> , 10(4): 339-358, 2000.		
	B11	LAVELLE <i>et al.</i> Improved methods for the delivery of liposome-sequestered RNA into eucaryotic cells. <i>Arch Biochem Biophys</i> . 215(2):486-97, 1982.		
	B12	LICHTENBERG <i>et al.</i> Liposomes: Preparation, Characterization and Preservation. <i>Meth Biochem Anal</i> . 33:337-462, 1988.		
	B13	MANNINO <i>et al.</i> Liposome mediated gene transfer. <i>Biotechniques</i> . 6(7):682-90, 1988.		
	B14	MANNINO <i>et al.</i> Liposomes as adjuvants for peptides: Preparation and use of immunogenic peptide-phospholipid complexes. <i>Liposome Technology</i> , 2 <sup>nd</sup> Edition. 2:167-184, 1993.		
	B15	MANNINO <i>et al.</i> Lipid matrix-based vaccines for mucosal and systemic immunization. <i>Pharm Biotechnol</i> . 6:363-87, 1995.		
	B16	MANNINO <i>et al.</i> Antigen cochleate preparations for oral and systemic vaccinations. <i>New Gen Vaccines</i> 2 <sup>nd</sup> ed., Ch 18, pgs. 229-39, 1997.		
	B17	MORI <i>et al.</i> Immunotargeting of liposomes containing lipophilic antitumor prodrugs. <i>Pharm Res</i> . 10(4):507-14, 1993.		
	B18	PAPAHADJOPOULOS <i>et al.</i> Cochleate lipid cylinders formation by fusion of unilamellar lipid vesicles. <i>Biochim Biophys Acta</i> . 394(3): 483-491, 1975.		
	B19	PAPAHADJOPOULOS <i>et al.</i> The use of lipid vesicles for introducing macromolecules into cells. <i>Prot Turnover Lysosome Funct</i> . 543-60, 1978.		
	B20	PARKER <i>et al.</i> In vivo and in vitro antiproliferative effects of antisense interleukin 10 oligonucleotides. <i>Meth Enzym: Antisense Tech, Part B</i> 314: 411-29, 1999.		
	B21	SANTANGELO <i>et al.</i> Efficacy of oral cochleate-amphotericin B in a mouse model of systemic candidiasis. <i>Antimicrob. Agents Chemother</i> , pgs. 2356-2360, 2000.		
Examiner Signature				Date Considered

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				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	3	of	3	Attorney Docket Number	BSZ-017

	C1	ZARIF <i>et al.</i> , Amphotericin B cochleates as a novel oral delivery system for the treatment of fungal infection. <i>Proceedings of the International Symposium on Controlled Release of Bioactive Materials</i> , Illinois: Controlled Release Society, pgs. 964-965, 1999.	
	C2	ZARIF <i>et al.</i> Antifungal activity of amphotericin B cochleates against <i>Candida albicans</i> infection in a mouse model. <i>Antimicrob. Agents Chemother</i> 1463-1469, 2000.	
	C3	ZARIF <i>et al.</i> Cochleates: New lipid based drug delivery system. <i>J. Liposome Res</i> 10(4): 523-538, 2000.	
	C4	ZARIF <i>et al.</i> Elongated supramolecular assemblies in drug delivery. <i>J. Controlled Rel</i> 81: 7-23, 2002.	
	C5	International Search Report for Application No. PCT/US2004/001236.	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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